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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/237,291   | 01/25/1999  | JUDY CAROL YOUNG     | SYS-2068            | 9391             |
| 1095   | 7590        | 07/26/2006           | EXAMINER            |                  |
| NOVARTIS<br>CORPORATE INTELLECTUAL PROPERTY<br>ONE HEALTH PLAZA 104/3<br>EAST HANOVER, NJ 07936-1080 |             |                      | MONTANARI, DAVID A  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1632                |                  |

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/237,291             | YOUNG ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | David Montanari        | 1632                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-20, 23-27, 31-34, 37-43, 46-50 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-20, 23-27, 31-34, 37-43, 46-50, and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicants arguments and amendments filed 5/3/2006 have been entered.
2. Claims 18-20,23-27,31-34,37-43,46-50, and 52 are examined in the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20, 23-27, 31-34, 37-43, 46-47, and 52 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dao et al. (01/15/1997, Blood, Vol. 89, pgs. 446-456) in view of Young et al. (09/01/1996, Blood, Vol. 88, pgs. 1619-1631) for reasons of record in the office action mailed 11/03/2005.

### ***Response to Arguments***

Applicants argue in amendment filed 5/3/2006 that the claimed method for obtaining genetically modified human pluripotent hematopoietic stem cells is not taught in the art of record to motivate the ordinary artisan to make and use the claimed invention. Applicants arguments specifically center around the use of TPO, and that the fact that the use of TPO promotes differentiation in hematopoietic stem cell, and that the Young et al. reference teaches away from

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the applicants claimed invention. Applicant argue, with reference to claims 18 and 52, that Dao fails to teach or suggest the use of FLT3 ligand in combination with mpl ligand and fibronectin. These arguments are not persuasive. Regarding TPO, as taught by Young et al., applicant has taken the position that by using TPO the ordinary artisan would not be motivated to use TPO in the claimed method because TPO promotes differentiation. However, only in claims 20 and 40 is the limitation where the cells do not differentiate recited, where TPO is present. Further claims 20 and 40 are drawn to the concentration range of interleukin-3 with regard to a lack of differentiation in human pluripotent hematopoietic stem cells. Independent claim 18 and 23 recite the limitation “and can differentiate into any hematopoietic cell type”, this is not the same as cells remaining undifferentiated. The ordinary artisan would have been motivated by the teachings of Young and Dao to use TPO since the cells are not required to remain undifferentiated. Clearly a thorough reading of Dao and Young would teach that the use of the TPO, as well as mpl, FLT3, fibronectin, IL-6, is eventually used to differentiate the cells to a dedicated lineage since the purpose of stem cells is to promote differentiation to a specific cell lineage of interest. Since the majority of claims do not require the cells to remain undifferentiated the ordinary artisan would have been provided motivation by Young to use TPO. Regarding Dao, the ordinary artisan would have been motivated to use FLT3 ligand in combination with a mpl ligand and fibronectin as taught by Young since Dao teaches that FLT3 stimulates proliferation of cells, and might be essential to viability absent stromal support. At issue is that though the applicant argues that the ordinary artisan would not have been motivated to use TPO in culture to maintain human pluripotent hematopoietic stem cell undifferentiated, none of the instant claims require this limitation. As discussed above the instant claims at most

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require an undifferentiated state with regard to the concentration range of interleukin-3. Thus for reasons of record and above the rejection is maintained.

No claims are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.

A handwritten signature in black ink, appearing to read 'Dave Trong Nguyen', with a long horizontal flourish extending to the right.

**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**